

PATENT APPLN. NO. 10/588,733
RESPONSE UNDER 37 C.F.R. §1.111

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REMARKS

The invention defined by the claims of the present application is a solid formulation for dialysis, which contains sodium chloride, calcium chloride, magnesium chloride, and sodium acetate as electrolyte components, and comprises a mixture of:

first particles having a coating layer containing electrolyte components except calcium chloride, on surfaces of sodium chloride particles; and

second particles having a coating layer containing electrolyte components except magnesium chloride, on the surfaces of sodium chloride particles.

The solid formulation for dialysis of the present invention is used for a double-preparation type bicarbonate solid formulation for dialysis, which is formed of a formulation that contains sodium bicarbonate and a formulation that contains an electrolyte other than sodium bicarbonate, acid, and glucose, or a triple-preparation type bicarbonate solid formulation for dialysis, which is formed of a formulation that contains sodium bicarbonate, a formulation that contains an electrolyte other than sodium bicarbonate and acid, and a formulation that contains glucose.

The inventors of the solid formulation for dialysis of the present invention discovered that in the solid formulation for

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dialysis of the present invention in which calcium chloride and magnesium chloride, which are highly hygroscopic, are present as different particles (e.g., granules), aggregation or consolidation between particles due to moisture absorption thereof can be prevented, as compared with the conventional formulations in which calcium chloride and magnesium chloride coexist in the same particles. Additionally, the content of each component in the formulation of the present invention becomes uniform, so it can be quickly dissolved in water when used.

In the Action, the Office rejects the claims of the application over Kai et al., U.S. Patent No. 6,464,977 ("Kai"). Kai discloses a solid preparation for dialysis, which is representative of the prior art, and comprises a mixture of:

(a) a first composition which comprises core particles comprising particles of sodium chloride and a coating layer covering the core particles and containing one or more electrolytes selected from the group consisting of calcium chloride, magnesium chloride, potassium chloride and sodium acetate,

(b) particles of a second composition which comprises core particles comprising particles of a sugar and a coating layer covering the core particles and containing one or more electrolytes selected from the group consisting of sodium chloride, calcium

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chloride, magnesium chloride, potassium chloride and sodium acetate, and

(c) an acid.

The Office asserts that the difference between Kai and the claimed invention is that Kai "does not expressly disclose exclusion of calcium chloride in the first particle and [the exclusion of] magnesium chloride in the second particle." (Action, page 2, lines 6 and 7 from the bottom of the page. The Office concludes that the prior art suggests such exclusion because:

"Kai et al. discloses that calcium chloride and magnesium chloride can be selected as coatings for the sodium chloride core. As such, one of ordinary skill in the art would have expected sodium chloride particles which do not contain calcium chloride coating and sodium chloride particles which do not contain magnesium chloride coating would be suitable for use in the dry dialysate."

(Action, page 2, lines 1-5 from the bottom of the page).

The above-quoted statement is an unsupported conclusion that is insufficient to support a case of prima facie obviousness of the claimed invention under 35 U.S.C. § 103(a). Absent from the conclusion is an explanation of why one of ordinary skill in the art would have expected a mixture of sodium chloride particles

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coated with electrolytes which do not contain calcium chloride and sodium chloride particles coated with electrolytes which do not contain magnesium chloride to be suitable for use in a dry dialysate with predictable results. In the absence of such reasoning the Office has not provided the rationale underpinning required to support its position.

Moreover, the Office is implicitly suggesting that one of ordinary skill in the art would have expected particles of sodium chloride coated with both calcium chloride and magnesium chloride to provide substantially equivalent results to the use of a mixture of particles of sodium chloride coated with calcium chloride (without magnesium chloride) and particles of sodium chloride coated with magnesium chloride (without calcium chloride).

However, the comparative data in the application rebut such a conclusion. The data show that the solid formulation for dialysis of the present invention which contains sodium chloride, calcium chloride, magnesium chloride, and sodium acetate as electrolyte components, and comprises a mixture of first particles having a coating layer containing electrolyte components except calcium chloride, on surfaces of sodium chloride particles; and second particles having a coating layer containing electrolyte components except magnesium chloride, on the surfaces of sodium chloride

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particles, provides materially different and superior stability and dissolution times. (See, for example, the data for Examples 1 and 3 and Comparative Examples 1 and 2 in Tables 3 and 4 of the present application).

The comparative data in the application rebut the conclusion of the Office and support the non-obviousness of the solid formulation for dialysis of the present invention as defined in the claims of the application. Removal of the 35 U.S.C. § 103(a) rejection is in order.

The foregoing is believed to be a complete and proper response to the Office Action dated June 24, 2009.

In the event that this paper is not considered to be timely filed, applicants hereby petition for an appropriate extension of time. The fee for any such extension and any additional required fees may be charged to Deposit Account No. 111833.

Respectfully submitted,
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